

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| BRISTOL-MYERS SQUIBB, CO. | : | Civil Action No.: 10-5810 (MLC) |
| Plaintiff, | : | |
| v. | : | PRETRIAL SCHEDULING ORDER |
| APOTEX, INC., et al., | : | |
| Defendants. | : | |

This matter having come before the Court during an initial conference on April 12, 2011, pursuant to Fed. R. Civ. P. 16; Christine Gannon, Esq., of Connell Foley LLP, with Leora Ben-Ami, Esq., and Benjamin Hsing, Esq., of Kaye Scholer LLP, appearing on behalf of Plaintiff; and Arnold Calmann, Esq., and Geri Albin, Esq., of Saiber LLC, with Paul Molino, Esq., Tara Raghavan, Esq., and Luke Shannon, Esq., of Rakoczy Molino Mazzochi Siwik LLP appearing on behalf of Defendants; and the Court having considered the positions of the parties; and good cause having been shown;

IT IS on this 6th day of May, 2011,

ORDERED THAT the following schedule shall apply to this matter which arises under 21 U.S.C. § 355 (commonly referred to as “the Hatch-Waxman Act”) and involves a Paragraph IV certification:

1. (a) By April 11, 2011, the Defendant(s) shall produce to Plaintiff(s) the entire Abbreviated New Drug Application or New Drug Application that is the basis of the case in question.

(b) By July 5, 2011, the Defendant(s) shall provide to Plaintiff(s) the written basis for their “Invalidity Contentions,” for any patents referred to in Defendant(s) Paragraph IV Certification which shall contain all disclosures required by Paragraph 2 below.

(c) Any “Invalidity Contentions” disclosed shall be accompanied by the production of documents required under Paragraph 3 below.

(d) By July 5, 2011, the Defendant(s) shall provide to Plaintiff(s) the written basis for their “Non-Infringement Contentions,” for any patents referred to in Defendant(s) Paragraph IV Certification which shall include a claim chart identifying each claim at issue in the case and each limitation of each claim at issue. The claim chart shall specifically identify for each claim which claim limitation(s) are literally absent from the Defendant(s) allegedly infringing Abbreviated New Drug Application or New Drug Application.

(e) Any “Non-Infringement Contentions” disclosed shall be accompanied by the production of any document or thing that the Defendant(s) intend to rely on in defense against any infringement contentions by Plaintiff(s).

(f) By August 19, 2011, Plaintiff(s) shall provide Defendant(s) with a “Disclosure of Asserted Claims and Infringement Contentions,” for all patents referred to in Defendant(s) Paragraph IV Certification, which shall contain all disclosures required by Paragraph 4 below.

(g) Any “Disclosure of Asserted Claims and Infringement Contentions,” shall be accompanied by the production of documents required by Paragraph 5 below.

2. “Invalidity Contentions” shall contain the following information:

(a) The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious. Each prior art patent shall be identified by its number, country of origin, and date of issue. Each prior art publication shall be identified by its title, date of publication, and where feasible, author and publisher. Prior art under 35 U.S.C. § 102(b) shall be identified by specifying the item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known. Prior art under 35 U.S.C. § 102(f) shall be identified by providing the name of the person(s) from whom and the circumstances under which the invention or any part of it was derived. Prior art under 35 U.S.C. § 102(g) shall be identified by providing the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant(s);

(b) Whether each item of prior art anticipates each asserted claim or renders it obvious. If obviousness is alleged, an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness.

(c) A chart identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and

(d) Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims.

3. Document Production Accompanying Invalidity Contentions shall include:

(a) Source code, specifications, schematics, flow charts, artwork formulas, or other documentation sufficient to show the operation, composition, or structure of any aspects or elements of each accused apparatus, product, device, process, method, act, or other instrumentality (“Accused Instrumentality”) identified by the patent claimant; and

(b) A copy or sample of the prior art identified pursuant to this Order which does not

appear in the file history of the patent(s) at issue. To the extent any such item is not in English, an English translation of the portion(s) relied upon shall be produced.

The producing party shall separately identify by production number which documents correspond to each category.

4. "Disclosure of Asserted Claims and Infringement Contentions" shall contain the following information:

(a) Each claim of each patent in suit that is allegedly infringed by each opposing party, including for each claim the applicable statutory subsections of 35 U.S.C. § 271 asserted;

(b) Separately for each asserted claim, each accused apparatus, product, device, process, method, act, or other instrumentality ("Accused Instrumentality") of each opposing party of which the party is aware. This identification shall be as specific as possible. Each product, device, and apparatus shall be identified by name or model number, if known. Each method or process shall be identified by name, if known, or by any product, device, or apparatus which, when used, allegedly results in the practice of the claimed method or process;

(c) A chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function;

(d) For each claim which is alleged to have been indirectly infringed, an identification of any direct infringement and a description of the acts of the alleged indirect infringer that contribute to or are inducing that direct infringement. Insofar as alleged direct infringement is based on joint acts of multiple parties, the role of each such party in the direct infringement must be described;

(e) Whether each limitation of each asserted claim is alleged to be literally present or present under the doctrine of equivalents in the Accused Instrumentality;

(f) For any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled;

(g) If a party claiming patent infringement wishes to preserve the right to rely, for any purpose, on the assertion that its own apparatus, product, device, process, method, act, or other instrumentality practices the claimed invention, the party shall identify, separately for each asserted claim, each such apparatus, product, device, process, method, act, or other instrumentality that incorporates or reflects that particular claim; and

(h) If a party claiming patent infringement alleges willful infringement, the basis for such allegation.

5. Document Production Accompanying the "Disclosure of Asserted Claims and Infringement Contentions," shall include:

(a) Documents (e.g., contracts, purchase orders, invoices, advertisements, marketing materials, offer letters, beta site testing agreements, and third party or joint development agreements) sufficient to evidence each discussion with, disclosure to, or other manner of providing to a third party, or sale of or offer to sell, or any public use of, the claimed invention prior to the date of application for the patent in suit. A party's production of a document as required herein shall not constitute an admission that such document evidences or is prior art under 35 U.S.C. § 102;

(b) All documents evidencing the conception, reduction to practice, design, and development of each claimed invention, which were created on or before the date of application for the patent in suit or the priority date identified;

(c) A copy of the file history for each patent in suit (or so much thereof as is in the possession of the patentee); and

(d) All documents evidencing ownership of the patent rights by the party asserting patent infringement.

The producing party shall separately identify by production number which documents correspond to each category.

6. Amendment to Contentions:

Amendment of the Infringement Contentions or the Invalidity Contentions may be made only by order of the Court upon a timely application and showing of good cause. The application shall disclose whether the adverse party consents or objects. Non-exhaustive examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause include: (a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material prior art despite earlier diligent search; and (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contentions. The duty to supplement discovery responses under Fed. R. Civ. P. 26(e) does not excuse the need to obtain leave of Court to amend contentions.

7. Advice of Counsel:

Unless otherwise ordered by the Court, not later than 30 days after entry of the Court's claim construction order, or upon such other date as set by the Court, each party relying upon advice of counsel as part of a patent-related claim or defense for any reason shall:

(a) Produce or make available for inspection and copying any written advice and documents related thereto for which the attorney-client and work product protection have been waived;

(b) Provide a written summary of any oral advice and produce or make available for inspection and copying that summary and documents related thereto for which the attorney-client

and work product protection have been waived; and

(c) Serve a privilege log identifying any documents other than those identified in subpart (a) above, except those authored by counsel acting solely as trial counsel, relating to the subject matter of the advice which the party is withholding on the grounds of attorney-client privilege or work product protection.

A party who does not comply with these requirements shall not be permitted to rely on advice of counsel for any purpose absent a stipulation of all parties or by order of the Court.

8. Exchange of Proposed Terms for Construction:

(a) By September 2, 2011, each party shall serve on each other party a list of claim terms which that party contends should be construed by the Court, and identify any claim term which that party contends should be governed by 35 U.S.C. § 112(6).

(b) The parties shall thereafter meet and confer for the purposes of limiting the terms in dispute by narrowing or resolving differences and facilitating the ultimate preparation of a Joint Claim Construction and Prehearing Statement.

9. Exchange of Preliminary Claim Constructions and Extrinsic Evidence.

(a) By September 23, 2011, the parties shall simultaneously exchange preliminary proposed constructions of each term identified by any party for claim construction. Each such “Preliminary Claim Construction” shall also, for each term which any party contends is governed by 35 U.S.C. § 112(6), identify the structure(s), act(s), or material(s) corresponding to that term's function.

(b) At the same time the parties exchange their respective “Preliminary Claim Constructions,” each party shall also identify all references from the specification or prosecution history that support its preliminary proposed construction and designate any supporting extrinsic evidence including, without limitation, dictionary definitions, citations to learned treatises and prior art and testimony of all witnesses including expert witnesses. Extrinsic evidence shall be identified by production number or by producing a copy if not previously produced. With respect to all witnesses including experts, the identifying party shall also provide a description of the substance of that witness' proposed testimony that includes a listing of any opinions to be rendered in connection with claim construction.

(c) The parties shall thereafter meet and confer for the purposes of narrowing the issues and finalizing preparation of a Joint Claim Construction and Prehearing Statement.

10. Joint Claim Construction and Prehearing Statement:

By October 24, 2011, the parties shall complete and file a Joint Claim Construction and Prehearing Statement, which shall contain the following information:

(a) The construction of those terms on which the parties agree;

(b) Each party's proposed construction of each disputed term, together with an identification of all references from the intrinsic evidence that support that construction, and an identification of any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction, including, but not limited to, as permitted by law, dictionary definitions, citations to learned treatises and prior art, and testimony of all witnesses including experts;

(c) An identification of the terms whose construction will be most significant to the resolution of the case. The parties shall also identify any term whose construction will be case or claim dispositive or substantially conducive to promoting settlement, and the reasons therefor;

(d) The anticipated length of time necessary for the Claim Construction Hearing; and

(e) Whether any party proposes to call one or more witnesses at the Claim Construction Hearing, the identity of each such witness, and for each witness, a summary of his or her testimony including, for any expert, each opinion to be offered related to claim construction.

11. Completion of Claim Construction Discovery:

By November 23, 2011, the parties shall complete all discovery relating to claim construction, including any depositions with respect to claim construction of any witnesses, other than experts, identified in the Preliminary Claim Construction statement or Joint Claim Construction and Prehearing Statement.

12. Claim Construction Submissions:

(a) By December 8, 2011, the parties shall contemporaneously file and serve their opening *Markman* briefs and any evidence supporting claim construction, including experts' certifications or declarations ("Opening *Markman* Submissions").

(b) Unless otherwise ordered by the Court, any discovery from an expert witness who submitted a certification or declaration shall be concluded by January 9, 2012.

(c) The parties shall contemporaneously file and serve responding *Markman* briefs and any evidence supporting claim construction, including any responding experts' certifications or declarations, by February 6, 2012.

13. A Claim Construction Hearing shall be set by the Court at a later date.

14. Defendants may submit a letter brief by no later than April 27, 2011, requesting to bifurcate Plaintiff's willfulness and exceptional-case claims and to stay discovery on those issues until after liability has been decided. Plaintiff may submit a written response to such letter brief by no later than May 11, 2011.

15. A telephone conference shall be held on July 11, 2011 at 9:30 A.M. Defendants shall initiate the call.

16. The remaining schedule shall be set by the Court following a Claim Construction Ruling.

17. Counsel will confer in an attempt to resolve any discovery or case management disputes before making such dispute the subject of a motion. No discovery motion will be entertained absent counsel's full compliance with L. Civ. R. 37.1(a)(1); *see also* L. Civ. R. 16.1(f).

18. In accordance with Fed. R. Civ. P. 30, the parties shall be limited to ten depositions, per side, except upon leave of Court. In accordance with Fed. R. Civ. P. 33, the parties shall be limited to twenty-five interrogatories, (including all subparts), per party, except upon leave of Court.

19. A settlement conference shall be conducted on a date to be set by the Court. Prior to the settlement conference, each party is to deliver to the Court a confidential letter, NOT to exceed 5 pages in total, summarizing the relevant facts, the respective legal positions, status of the case, and the client's position of settlement. Trial counsel and clients with full settlement authority are to be present IN PERSON at the conference. Any failure in this regard shall result in the imposition of sanctions.

20. Any proposed confidentiality order agreed to by the parties must be accompanied by a separate statement showing specific good cause for the entry of the order and must comply with L. Civ. R. 5.3.

21. The parties are advised that the Court has various audio/visual and evidence presentation equipment available for use at trial at no cost to the parties. This equipment includes an evidence presentation system, which consists of a document camera and a projector. The projector may be used to display images which originate from a variety of sources, including television, VCR and personal computer. The document camera may be used to display documents, photographs, charts, transparencies and small objects. For further information, please contact the Courtroom Deputy Ivannya Jimenez.

22. An original copy of any letter memoranda that is faxed or emailed to Chambers should NOT be mailed to Chambers, unless specifically advised otherwise. All proposed orders and letter memoranda emailed to Chambers should be in WordPerfect or MS Word format and emailed to: lhg_orders@njd.uscourts.gov. Any filings with the Clerk of the Court should be in PDF format.

23. Counsel are invited to use the George H. Barlow Attorney Conference Room located on the third floor of the Courthouse Annex. The room is equipped with telephones, laptop and printer access, copier, and facsimile.



LOIS H. GOODMAN
United States Magistrate Judge